STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 14

Advertising

CHAPTER 2

Requirements relating to advertising

Advertising to persons qualified to prescribe or supply etc

General requirements

294.—(1) This regulation applies to an advertisement that—

(a) relates to a medicinal product; and

(b) is wholly or mainly directed at persons qualified to prescribe or supply such products.

(2) A person may not publish an advertisement to which this regulation applies unless—

(a) subject to **[**F1paragraphs (2C) and (3),**]** it contains the particulars set out in paragraphs 1 to 8 of Schedule 30; and

(b) in the case of a written advertisement, it is in accordance with paragraph 9 of that Schedule.

[F2(2A) By way of an exception to paragraph (2), in the case of an advertisement that relates to a pharmacy medicine or a medicinal product subject to general sale, a person may publish the advertisement if it contains—

(a) the particulars set out in paragraphs 2 to 6 of Schedule 30; and

(b) the statement "Information about this product, including adverse reactions, precautions, contra-indications, and method of use can be found at:"; accompanied by

(c) a website address that corresponds to that statement.

(2B) The website at the address mentioned in paragraph (2A)(c) must make available—

(a) the particulars set out in paragraphs 1 to 8 of Schedule 30; or

(b) a copy of the summary of the product characteristics.**]**

[F3(2C) Paragraph 1 of Schedule 30 does not apply in the case of a product in relation to which there is in force an authorisation by the licensing authority on a temporary basis under regulation 174.**]**

(3) In the case of an advertisement that is not a written advertisement, those particulars may alternatively be made available in written form to all persons to whom the advertisement is made available.

(4) This regulation—

(a) does not apply to an advertisement to which regulation 295 (abbreviated advertisements) applies;

(b) does not apply to oral representations made by medical sales representatives to which regulation 299 (medical sales representatives) applies; and

(c) is subject to regulations 296 (exception for advertisements intended as a reminder) and 301 (advertisements for registered homoeopathic medicinal products).

[F4(5) In the case of an advertisement which relates to a medicinal product for sale or supply—

(a) in Northern Ireland only, the requirements of this regulation must be met in relation to the product for sale or supply in Northern Ireland,

(b) in Great Britain only, the requirements of this regulation must be met in relation to the product for sale or supply in Great Britain, and

(c) in the whole of the United Kingdom, the requirements of this regulation must be met in relation to both—

(i) the product for sale or supply in Great Britain, and

(ii) the product for sale or supply in Northern Ireland.**]**

Textual Amendments

F1 Words in reg. 294(2)(a) substituted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **26(2)** and words in reg. 294(2)(a) substituted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **26(2)**

F2 Reg. 294(2A)(2B) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **24(2)** and reg. 294(2A)(2B) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **24(2)**

F3 Reg. 294(2C) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **26(3)** and reg. 294(2C) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **26(3)**

F4 Reg. 294(5) inserted (31.12.20200 by S.I. 2019/775, **reg. 214A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 172**)

Abbreviated advertisements

295.—(1) This regulation applies to an abbreviated advertisement that—

(a) relates to a medicinal product; and

(b) is wholly or mainly directed at persons qualified to prescribe or supply such products.

(2) A person may not issue an abbreviated advertisement to which this regulation applies unless it contains—

(a) the particulars set out in paragraphs 2 to 6 of Schedule 30 (particulars for advertisements to persons qualified to prescribe or supply);

(b) the statement "Information about this product, including adverse reactions, precautions, contra-indications, and method of use can be found at:"; accompanied by

(c) a web site address that corresponds to that statement; and

[F5(d) the name and address of the holder **[**F6of either the temporary authorisation or**]**—

(i) in the case of a medicinal product for sale or supply in Great Britain, of the UKMA(GB), UKMA(UK), COR(GB), COR(UK), THR(GB) or THR(UK) for the medicinal product, or

(ii) in the case of a medicinal product for sale or supply in Northern Ireland, the name and address of the holder of the UKMA(NI), UKMA(UK), COR(NI), COR(UK), THR(NI), THR(UK), EU marketing authorisation, or Article 126a authorisation for the medicinal product,

or the business name and address of the part of the holder's business that is responsible for the sale or supply of the medicinal product.**]**

(3) The web site at the address mentioned in sub-paragraph (2)(c) must make available—

(a) the particulars set out in Schedule 30; or

(b) a copy of the summary of the product characteristics.

(4) In this regulation, "abbreviated advertisement" means an advertisement, other than a loose insert, that—

(a) does not exceed 420 square centimetres in size; and

(b) appears in a publication sent or delivered wholly or mainly to persons qualified to prescribe or supply medicinal products.

[F7(4A) In the application of this regulation to a medicinal product for sale or supply—

(a) in Northern Ireland only, the requirements of this regulation must be met in relation to the product for sale or supply in Northern Ireland,

(b) in Great Britain only, the requirements of this regulation must be met in relation to the product for sale or supply in Great Britain, and

(c) in the whole of the United Kingdom, the requirements of this regulation must be met in relation to both—

(i) the product for sale or supply in Great Britain, and

(ii) the product for sale or supply in Northern Ireland.**]**

(5) This regulation is subject to regulation 301 (advertisements for registered homoeopathic medicinal products).

Textual Amendments

F5 Reg. 295(2)(d) substituted (31.12.2020) by S.I. 2019/775, **reg. 215(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 173**)

F6 Words in reg. 295(2)(d) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **14** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **14**

F7 Reg. 295(4A) inserted (31.12.2020) by S.I. 2019/775, **reg. 215(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 173**)

Exception for advertisements intended as a reminder

296. Regulations 291 (form and content of advertisement) and 294 (general requirements) do not apply to an advertisement relating to a medicinal product if the advertisement is intended solely as a reminder of the product and consists solely of—

(a) in the case of a product other than a homoeopathic medicinal product to which a certificate of registration relates, its name, international non-proprietary name or trademark; and

(b) in the case of a homoeopathic medicinal product to which a certificate of registration relates, its name, international non-proprietary name, invented name or trademark or the scientific name of the stock or stocks from which it is derived.

Written material accompanying promotions

297.—(1) A person may not as part of the promotion of a medicinal product send or deliver any written material to a person qualified to prescribe or supply medicinal products unless the material—

(a) **[**[F8]subject to paragraph (1A),**]** contains particulars in accordance with all the paragraphs of Schedule 30; and

(b) states the date on which it was drawn up or last revised.

[[F9](1A) Paragraph 1 of Schedule 30 does not apply in the case of a product in relation to which there is in force an authorisation by the licensing authority on a temporary basis under regulation 174.**]**

(2) A person may not include any information in written material to which paragraph (1) applies unless it—

(a) is accurate;

(b) is up-to-date;

(c) can be verified; and

(d) is sufficiently complete to enable the recipient to form an opinion of the therapeutic value of the product to which it relates.

(3) A person may not include any illustrative material in written material to which paragraph (1) applies unless—

(a) the illustrative material is accurately reproduced; and

(b) the written material indicates the precise source of the illustrative material.

(4) In this regulation "illustrative material" means a quotation, table or any other illustrative material taken from a medical journal or other scientific work.

Textual Amendments

F8 Words in reg. 297(1)(a) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **28(2)** and words in reg. 297(1)(a) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **28(2)**

F9 Reg. 297(1A) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **28(3)** and reg. 297(1A) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **28(3)**

Free samples for persons qualified to prescribe or supply medicinal products

298.—(1) A person ("the supplier") may not supply a free sample of a medicinal product to another person ("the recipient") unless the following conditions are met.

(2) Condition A is that the recipient—

(a) is qualified to prescribe medicinal products; and

(b) receives the sample for the purpose of acquiring experience in dealing with the product in question.

(3) Condition B is that the sample is supplied to the recipient—

(a) on an exceptional basis; and

(b) in response to a request from, and signed and dated by, the recipient.

(4) Condition C is that, taking the year in which the sample is supplied as a whole, only a limited number of samples of the product in question are supplied to the recipient in that year.

(5) Condition D is that the sample—

[F10(a) is no larger than the smallest presentation of the product that is available for sale—

(i) in the case of a medicinal product for sale or supply in Great Britain, in Great Britain, or

(ii) in the case of a medicinal product for sale or supply in Northern Ireland, in Northern Ireland;**]**

(b) is marked "free medical sample – not for resale" or bears a similar description; and

(c) is accompanied by a copy of the summary of the product characteristics.

(6) Condition E is that the sample does not contain—

(a) a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention); or

(b) a substance which is listed in any of Schedules I to IV to the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention).

(7) Condition F is that the supplier maintains an adequate system of control and accountability in relation to the supply of free samples.

Textual Amendments

F10 Reg. 298(5)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 215A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 174**)

Medical sales representatives

299.—(1) This regulation applies in relation to the promotion by a medical sales representative of medicinal products to persons qualified to prescribe or supply such products.

(2) During each visit for promotional purposes the representative must give to, or have available for, each person visited a copy of the summary of the product characteristics for each product promoted.

(3) The representative must report all information, with particular reference to any adverse reactions, that—

(a) is received from persons visited for promotional purposes; and

(b) relates to the use of a product promoted,

to the scientific service established in accordance with regulation 281(2) by the holder of the **[**F11UK marketing authorisation, EU marketing authorisation**]** certificate of registration, traditional herbal registration or Article 126a authorisation for the product.

Textual Amendments

F11 Words in reg. 299(3) substituted (31.12.2020) by S.I. 2019/775, **reg. 217** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 176**); 2020 c. 1, **Sch. 5 para. 1(1)**

Inducements and hospitality

300.—(1) A person may not, in connection with the promotion of medicinal products to persons qualified to prescribe or supply them, supply, offer, or promise any gift, pecuniary advantage or benefit unless it is—

(a) inexpensive; and

(b) relevant to the practice of medicine or pharmacy.

(2) A person may not provide hospitality at a meeting or event held for the purposes of the promotion of a medicinal product unless—

(a) the hospitality is strictly limited to the main purposes of the meeting or event; and

(b) the person to whom it is provided or offered is a health care professional.

(3) Nothing in this regulation shall prevent any person providing hospitality at an event held for purely professional or scientific purposes provided that—

(a) the hospitality is strictly limited to the main scientific objective of the event; and

(b) the person to whom it is provided or offered is a health care professional.

(4) A person qualified to prescribe or supply medicinal products may not solicit or accept any gift, pecuniary advantage, benefit or hospitality that is prohibited by this regulation.

(5) In this regulation "hospitality" includes—

(a) sponsorship of a person's attendance at a meeting or event; and

(b) the payment of travelling or accommodation expenses.

(6) This regulation does not apply in relation to measures or trade practices relating to prices, margins or discounts that were in existence on 1st January 1993.

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
The Human Medicines Regulations 2012, Cross Heading: Advertising to persons qualified to prescribe or supply etc is up to date with all changes known to be in force on or before 19 August 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.